K082339

510(k) SUMMARY

NOV 20 2008

EndoCross's ENABLER-P Support Catheter

Applicant's Information

Date Prepared:	October 15, 2008
Name and Address:	EndoCross Ltd New Industrial Park, Building 7 P.O.B 620, Yoqneam 20692, Israel
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Device Information

Classification:	DQY
Trade Name:	ENABLER-P Support Catheter
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter, 74 DQY / 21 CFR 870.1250

Predicate Devices

- Asahi Tornus Support Catheter manufactured by Asahi Intecc (K051772)
- Ultra -Thin SDS Balloon Dilatation Catheter manufactured by Boston Scientific Corporation (K011889)
- ILT MODEL C114NL2 with Advancing Mechanism manufactured by IntraLuminal Therapeutics Inc. (K001992)

Intended Use / Indications for Use

The ENABLER-P Support Catheter is intended to be used in conjunction with a steerable guidewire to access discrete regions of the peripheral vasculature and for guidewire exchange.

Technological Characteristics

The ENABLER-P Support Catheter is a dual-lumen intravascular catheter intended for percutaneous use. It is designed for use in conjunction with a 0.035" guidewire to gain access to locations within the cardiovascular system that are remote from the site of insertion. Once accessed, guidewires may be exchanged within the catheter. In addition, the ENABLER-P Support Catheter can provide distal anchoring and support the advancement of the guidewire.

The ENABLER-P Support Catheter is packaged in a Tyvek/Poly pouch to form a sterile barrier. The packaged catheter is sterilized by ethylene oxide gas. The ENABLER-P Support Catheter is provided "STERILE" and "Non-pyrogenic", and is intended for single use only.

The ENABLER-P Support Catheter is similar in basic materials, design, construction and mechanical performance to a combination of the predicate devices.

Biocompatibility And Performance Data

Biocompatibility testing, in vitro bench studies and animal studies were conducted to evaluate the biological and performance characteristics of the ENABLER-P Support Catheter. Biocompatibility test results indicate that the device materials are biocompatible. Performance test results indicate that the device satisfies functional performance requirements when used as indicated.

Substantial Equivalence

The ENABLER-P Support Catheter is substantially equivalent to the Asahi Tornus Support Catheter manufactured by Asahi Intecc, the Ultra -Thin SDS Balloon Dilatation Catheter manufactured by Boston Scientific Corp Ltd and the ILT MODEL C114NL2 with Advancing Mechanism manufactured by IntraLuminal Therapeutics Inc

The ENABLER-P Support Catheter has the same intended uses as the Asahi Tornus Support Catheter and similar technological characteristics as the Ultra -Thin SDS Balloon Dilatation Catheter and the ILT MODEL C114NL2 with Advancing Mechanism. The technological differences between the ENABLER-P Support Catheter and its predicate devices raise no new issues of safety or effectiveness.

Performance data demonstrate that the ENABLER-P Support Catheter is substantially equivalent to the Asahi Tornus Support Catheter, the Ultra -Thin SDS Balloon Dilatation Catheter and the ILT MODEL C114NL2 with Advancing Mechanism.

Thus, the ENABLER-P Support Catheter is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 20 2008

EndoCross, Ltd.
c/o John J. Smith, M.D., J.D.
Hogan & Hartson LLP
Columbia Square
555 Thirteenth Street N.W.
Washington, D.C. 20004

Re: K082339
Trade/Device Name: ENABLER-P Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (Two)
Product Code: DQY
Dated: October 17, 2008
Received: October 17, 2008

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K082339

Device Name: ENABLER-P Support Catheter

Intended Use / Indications for Use:

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Prescription Use ___√___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082339